JUL 1 3 2000

K001265

510(k) SUMMARY
Summary of Safety & Effectiveness

Submitter's Name & Address: Welch Allyn, Inc.
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153-0220

Contact Person & Telephone: David Klementowski
315-685-4133

Date Summary Prepared: April 14, 2000

Device Name:
Classification Name - None
Common/Usual Name - None
Proprietary Name - Welch Allyn Instrument Interface Module

Predicate Device: Hewlett-Packard Model M2376A Device Link System [Ref. 510(k) #K984194]

Device Description, Intended Use, and Effectiveness:

The Instrument Interface Module (IIM) is strictly a software product. It is designed to work with Microsoft Windows 95, 98, and NT It communicates with a specific set of medical devices via a standard synchronous RS-232 serial interface. The IIM is designed to specifically communicate with the following devices, but may be adapted for use with other similar types of devices in the future.

Welch Allyn Clinical Vital Signs Monitor
Welch Allyn Frequency Doubling Technology (FDT)
Welch Allyn/Schiller AT-10 EKG
Welch Allyn/Schiller SP-10 Spirometer

The IIM will request, receive, and parse alphanumeric and graphical observational data, and error messages from these various medical devices. It will then transfer this data to a Computerized Patient Record (CPR) system via HL7, DICOM and other industry standards.

The IIM will allow the user to configure a variety of medical devices with it upon installation, but will only communicate with a maximum of one medical device at a time. It will also display information to the user, using and active display module, in a manner that is consistent with the medical device used to capture the data.

The effectiveness of the IIM is the same as the predicate device noted above.

Technological Characteristics:

Reference Attachment #A (Chart of Predicate Device Comparison).

Safety:

Due to the fact this is a software device, it is considered very safe for both practitioner and patient. The device is non-contact, its operational technique is low risk, and it only collects and displays data and is not intended to be used as a diagnostic device.

Therefore, typical safety areas are not applicable (e.g., electrical and mechanical, biocompatibility, corrosion, explosion, temperature, and fire). However, the software has undergone the following reviews.

Risk Analysis
FMEA
Verification & Validation Tests

Summary of Effectiveness:

The determination of the IIM's effectiveness was established using:

1. Proven Windows technology and tools.
2. Specific medical devices noted under "Device Description, Intended Use, and Effectiveness".
3. Vendors who supply CPR systems to physicians and medical facilities.

The results of the testing and evaluations indicate that the Welch Allyn Instrument Interface Module meets the needs and expectations of the practitioners who will be using this software device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2000

David Klementowski
Regulatory Affairs Manager
Welch Allyn, Inc.
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153-0220

Re: K001265
Welch Allyn Instrument Interface Module
Regulatory Class: II (Two)
Product Code: 74 MWI
Dated: April 14, 2000
Received: April 19, 2000

Dear Mr. Klementowski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Devices
and Radiological Health

Enclosure

510(k) Number (if known): K001265

Device Name: Welch Allyn Instrument Interface Module

Indications for Use:

The IIM is designed to communicate with and collect data from diagnostic instruments. The data collected is then displayed for the user to verify before being sent to a computerized patient records (CPR) database where it is saved for later retrieval and review by a trained nurse or physician.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ___

(Optional Format 1-2-96)

Brian E. Fitzgerald

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001265